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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/063,568 | 05/02/2002 | Dan L. Eaton | P3230R1C48 | 9762 |
| 7590 | 06/17/2005 | | EXAMINER | |
| MARK T. KRESNAK, Ph.D. GENENTECH INC. 1 DNA WAY MS49 SOUTH SAN FRANCISCO, CA 94080 | | | GALVEZ, JAMES JASON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |
| | | | DATE MAILED: 06/17/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/063,568 | EATON ET AL. | |
| | Examiner | Art Unit | |
| | J. Jason Galvez | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 March 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

Upon further consideration, the finality of the previous office action is withdrawn.

It is noted that a Notice of Appeal and Appeal Brief have been filed. Applicant can

- 5 request a refund for the associated fee or leave it as credit for future appeals.

Rejections: Withdrawn

Specification

Objections to specification relating to embedded hyperlink and/or other form of

- 10 browser-executable code are withdrawn in response to amendments to the specification.

Claim Rejections - 35 USC § 101 and 112, 1st paragraph

Rejection of claims 1-5 under 35 U.S.C. § 101 and 112, first paragraph, relating

- 15 to the instant invention lacking a specific, substantial and well-established utility is withdrawn in response to cancellation and/or amendment of the claims.

Rejections: New Grounds

Claim Rejections - 35 USC § 112, 1st paragraph

- 20 Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-5 are drawn to an antibody directed to the polypeptides of SEQ ID NO: 60, which is encoded by the polynucleotides of SEQ ID NO: 59. The polynucleotides of 5 SEQ ID NO: 59 are “more highly expressed” in esophageal, lung and skin cancers compared to normal esophageal, lung and skin tissue, respectively (p. 140: Example 18). However, a perceived use of the polynucleotides does not confer the same use of antibodies directed to a polypeptide encoded by SEQ ID NO: 59, *i.e.* polypeptides of SEQ ID NO: 60. For example, it is well known that mRNA is not a reliable indicator of 10 increased protein expression (Haynes *et al.*, Electrophoresis 1998, Vol. 19(11): pp. 1862-1871, esp. p. 1863: section 2.1). Anderson *et al.* teach there is a very low correlation, if any at all, correlation coefficient of 0.48, between mRNA and protein level in liver (Electrophoresis 1997, Vol. 18(3-4): pp. 533-537, esp. p. 536: column 1, paragraph 1). Furthermore, Chen *et al.* teach that a correlation between protein 15 expression and mRNA level in tumor cells exist for only a subset of proteins (Mol Cell Proteomics 2002, Vol. 1(4): pp. 304-313, esp. p. 308-309). Scientific literature from several different fields has established that elevated protein levels cannot be accurately predicted solely on elevation of mRNA levels. As such, a person of ordinary skill in the art would not know how to use the invention without determining if protein levels and 20 mRNA levels are concordantly elevated. Without knowing if protein levels are also elevated a person of ordinary skill in the art would not know how to use antibodies directed to SEQ ID NO: 60 since no function has been shown to be attributed to the

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polypeptides of SEQ ID NO: 60. For the reasons set forth, without further guidance, a person of ordinary skill in the art would not be able to use the invention without undue experimentation.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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JJG
6/13/2005


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600